

Translation

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PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PH-1893-PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/012280	International filing date (day/month/year) 25 September 2003 (25.09.2003)	Priority date (day/month/year) 25 September 2002 (25.09.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/02, 9/64, 5/10, C07K 16/40, C12P 21/08, A61K 38/43, 39/395, A61P 7/02, G01N 33/532, 33/573, 33/577		
Applicant JURIDICAL FOUNDATION THE CHEMO-SERO-THERAPEUTIC RESEARCH INSTITUTE		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input checked="" type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) <u>1 DISK</u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 27 February 2004 (27.02.2004)	Date of completion of this report 16 June 2004 (16.06.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

** If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
See supplemental sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

☒ all parts.

☐ the parts relating to claims Nos. _____

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV.3

The inventions that are set forth in claims 1-29 pertain to anti-ADAMTS-13 antibodies.

On the other hand, the inventions that are set forth in claims 30-33 pertain to medicaments that contain ADAMTS-13.

The common technical feature among these inventions is ADAMTS-13. However, ADAMTS-13 is well known in the light of the documents that are presented in the following section; therefore, the inventions in question do not conform to the requirement of unity of invention.

(The present international application is considered to comprise two groups of inventions as disclosed in claims 1-29 and in claims 30-33, respectively.)

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-33	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-33	NO
Industrial applicability (IA)	Claims	1-33	YES
	Claims		NO

2. Citations and explanations

Document 1: Y. FUJIMURA et al., "Von Willebrand Factor-cleaving Protease and Upshaw-Shulman Syndrome," Int. J. Hematol., January 2002, Vol. 75, No. 1, pp. 25-34

Document 2: S. CAL et al., "Cloning, Expression Analysis, and Structural Characterization of Seven Novel Human ADAMTSs, a Family of Metalloproteinases with Disintegrin and Thrombospondin-1 Domains," Gene, January 2002, Vol. 283, No. 1-2, pp. 49-62

The inventions that are set forth in claims 1-33 do not involve an inventive step in the light of documents 1-2 cited in the international search report.

Documents 1-2 disclose an enzyme that specifically cleaves the Von Willebrand factor (ADAMTS-13).

Generally, in cases when a given protein that exhibits a specific function is known, it is common practice to produce an antibody against such a protein; therefore, it is considered to be easy for a person skilled in the art to conceive of using ADAMTS-13 in an antigen in order to produce an antibody against ADAMTS-13.

In addition, the same is true in relation to the feature of cloning the gene that codes the obtained

INTERNATIONAL P^{RI}MARY EXAMINATION REPORT

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antibody, the feature of using the antibody in a medicinal composition, and the feature of using the antibody in a preparation that contains a labelled protein.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 02/88366 A1	07 November 2002 (07.11.2002)	25 April 2002 (25.04.2002)	25 April 2001 (25.04.2001)
[EX]			

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)